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K092821

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5. 510(k) Summary

510(k) number: _____

510(k) submitter (owner):	A.M.I. Inc. 20 Main Street Suite 205 Natick MA 01760
official contact person authorized by the submitter:	Andrew Bendheim A.M.I. Inc. 20 Main Street Suite 205 Natick MA 01760 U.S.A. Phone: 508 655 1200
Date of preparation:	1. September 2009
Name of the device:	
trade or proprietary name:	A.M.I. TissueBag System
common or usual name:	TissueBag
classification name:	Endoscope and accessories (21 CFR 876.1500, Product Code GCJ)
Predicate Devices used for Substantial Equivalence:	**K 922123** / Autosuture Endoscopic Specimen Pouch / Specimen Retrieval Device

Device description:
The TissueBags are intended as receptacles for safe collection and removal of specimen during surgical procedures. Removal is accomplished by positioning the bag that serves as a receptacle for the specimen, close to the specimen that is intended to be removed. The bag opens, and the feeding-mouth is kept open automatically. Closure of the filled bag is done either by pulling back the complete device, or by pulling back an integrated purse string only.

The TissueBags comprise various types of retrieval bags, which share similarities of the basic functional principle, materials, Sterile-Barrier-Packaging, delivery status and sterilisation method. The TissueBags differ in the size of their bag (loading capacity), the availability of an integrated handle, respectively the need for being connected to an A.M.I.-dock Applicator pre-operatively and the possibility to disconnect the filled bag from the instrument.

Each TissueBag consists of a bag, a suspension mechanism, a protection sleeve and a handle, that is either an integrated part of the device or attached in terms of an A.M.I.-dock Applicator. One type of the TissueBags is additionally equipped with a purse string.

All TissueBags are designed to be applicable with 10 mm ports for minimally invasive surgery. They are disposable, delivered sterile as single use devices. Their Sterile-Barrier-Packaging consists of two independently sealed pouches made from Tyvek and PET-foil. Sterilisation by means of Radiation guarantees a Sterility Assurance Level of 10^{-6}. Biocompatibility evaluation has shown the TissueBags to meet the requirements of ISO 10993-1.

Comparison to predicate device (marketed device of similar type):
The TissueBag is substantially equivalent to the predicate device (marketed device of similar type) in design, basic functional principle, principle of operation and clinical effectiveness. The TissueBags provoke no new safety or effectiveness issues when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Agency for Medical Innovations, Inc.
% Mr. Andrew Bendheim
CEO
20 Main Street, Suite 205
Natick, Massachusetts 01760

FEB - 1 2010

Re: K092821
Trade/Device Name: A.M.I. TissueBag System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 22, 2010
Received: January 27, 2010

Dear Mr. Bendheim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K092821

Device Name: TissueBag

Indications for Use: The "TissueBags" are intended for safe collection and removal of specimen, such as appendix, gallbladder, myoma, cysts, ovaries, fibroid tumours and other tissues, and calculi during surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092821